

Considering Whether to Implement A Rapid Testing Program Using Rapid HIV Testing Technology: A Self-Assessment for Agencies

Table of Contents

Section One: Agency Capacity- see pages 1-3

Purpose: The purpose of this section is to help you examine agency infrastructure that needs to be in place in order to support a rapid HIV testing program.

- Sec 1, p. 1 Maintain confidential client records.
- Sec 1, p. 2 Staffing requirements.
- Sec 1, p. 3 Reimbursement issues.

Section Two: Operational Considerations- see pages 4-10

Purpose: The purpose of this section is to help you assess operational considerations that need to be in place in order to support a rapid HIV testing program.

- Sec 2, p. 4 Ensure appropriate physical space to conduct rapid testing.
- Sec 2, p. 5 Provide HIV test counseling in accordance with NYS Public Health Law.
- Sec 2, p. 6 Conduct and deliver results of confirmatory testing for all patients who test preliminary positive.
- Sec 2, p. 7 Refer all HIV positive clients to HIV primary and specialty medical care.
- Sec 2, p. 8 Provide assistance with partner notification, conduct the required domestic violence screening protocol and comply with HIV disease reporting requirements.
- Sec 2, p. 9 Refer HIV positive clients to a range of support services including: case management, alcohol and substance abuse treatment, entitlement programs, prevention, housing, legal services and others, as needed.
- Sec 2, p. 10 Implement an Exposure Control Plan to protect employees from exposure to bloodborne pathogens, ensure required staff training, provide staff vaccination against Hepatitis B and properly dispose of regulated medical waste.

Section Three: Laboratory Issues- see pages 11-13

Purpose: The purpose of this section is to help you assess laboratory quality assurance issues that are essential to ensure testing is being carried out correctly.

- Sec 3, p. 11 Register with NYS Clinical Laboratory Evaluation Program (CLEP), identify a qualified lab director, and obtain needed supplies.
- Sec 3, p. 12 Establish a comprehensive quality assurance plan that ensures proper supervision, outlines step-by step instructions and ensures staff competency in performing and interpreting the test.
- Sec 3, p. 13 Ensure that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse effects.

Section Four: Staff Training- see page 14

Purpose: The purpose of this section is to help you examine the entire range of staff training needs.

- Sec 4, p. 14 Staff should receive training in all aspects of the program including HIV test counseling, initial and annual confidentiality training, agency policies and procedures, how to conduct the test and bloodborne pathogens training.

Considering Whether to Implement A Rapid Testing Program: A Self-Assessment for Agencies

Instructions- Please Read Carefully: This self-assessment was developed for organizations that are considering implementing a comprehensive HIV counseling and testing. Read the required elements listed in column one of the page and then answer the associated key questions to consider in column two. After you have reviewed each key question on the page, complete the Feasibility Rating in column three. Transferring the feasibility rating from each page to the Quick Reference table (last page of document) will help highlight areas that require further attention.

Section One - Agency Capacity

Purpose: The purpose of this section is to help you examine agency infrastructure that needs to be in place in order to support a rapid HIV testing program.

1: 1 - Maintaining Confidential Client Records

Required Element	Key Questions to Consider	Feasibility Rating
<p>A confidential client record must be created and maintained for every client.</p> <p>Records should be kept in a secure location.</p> <p>Agency policies and procedures should outline which staff should have access to client records.</p> <p>Record keeping system should include:</p> <ul style="list-style-type: none"> - Client name - Contact information - Preliminary test result - Confirmatory result, if needed - Record of referrals and status of referrals - Counseling notes and/or progress notes <p>Staff should receive initial and annual training on confidentiality protections of Public Health Law Article 27-F and agency policies and procedures.</p>	<p>Does your agency currently maintain confidential client records?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Has your agency identified a secure location for records?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Has your agency identified which staff positions would need access to client records including HIV-specific information?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Can a record keeping system be developed to include the required elements outlined?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Do staff currently receive initial and annual training on Article 27-F and agency policies and procedures?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

1:2 - Staffing Requirements

Required Element	Key Questions to Consider
An HIV test must be ordered by a physician or other health care provider, such as a nurse practitioner (NP) or physician assistant (PA) who is legally authorized to use the results of these tests in the practice of his or her profession.	Does your agency have an MD, NP or PA on staff who is legally authorized to use the results of lab tests in the practice of his/her own profession? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
A limited testing site must have a lab director. Physicians, dentists, NPs or PAs with experience in laboratory testing may serve as lab director.	Does your agency have an MD, NP or PA on staff who would serve as the lab director? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <u>If the answer to either or both questions is no-</u> Is there a community health center, hospital or private MD office with an appropriately licensed provider who would be willing to serve as the authorizing provider and/or lab director? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
Staff that deliver HIV test counseling must be familiar with NYS counseling requirements.	Supervisors ensure staff are prepared to offer HIV counseling in accordance with NYS requirements by training staff in house or sending staff to a NYS approved or sponsored training. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
Staff that conduct the rapid test must be able to follow manufacturer's guidelines and agency policy and procedures.	Staff that conduct the rapid test have been trained or can be trained to follow guidelines and agency policy and procedure. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know

Feasibility Rating
<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

1:3 Reimbursement Issues

Required Element	Key Questions to Consider	Feasibility Rating
Each agency offering rapid testing for HIV should have a clear plan for how the program will be supported fiscally.	<p>Does your agency have a plan for covering the costs associated with rapid testing? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Has your agency conducted an assessment or gathered any information about the level of demand that may exist for rapid HIV testing in the community? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Has the agency determined roughly how many tests it would be able to conduct in a typical day, week or month? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Is the agency eligible to pursue enrollment in the HIV Primary Care Medicaid Program? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Has the agency explored whether grant funds may be used to support the program? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Does the agency have a plan for accounting for costs associated with implementing rapid HIV testing? Include costs associated with staffing, purchasing test kits, external controls, supplies, confirmatory testing, disposal of regulated medical waste and other costs. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Given your plan for fiscal support of the program, do you anticipate any financial barriers for clients to access the program? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

Section II - Operational Considerations

Purpose: The purpose of this section is to help you assess operational considerations that need to be in place in order to support a rapid HIV testing program.

2:4 Ensuring Appropriate Physical Space to Conduct Rapid Testing

Required Element	Key Questions to Consider	Feasibility Rating
Client counseling and processing of the rapid test should take place in a space that affords adequate privacy and confidentiality.	Counseling and test processing will take place in a space that affords the client privacy from being seen or overheard by others. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	Complete this column after reviewing column 1 and 2 on this page. Check One Box <input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category. <input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category. <input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category. <input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.
The rapid test must be performed on a clean, flat, level surface.	A clean, flat, level surface is available in all locations where testing will be performed. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
The rapid test must be read in a well-lit area.	The space where the test will be conducted and read is well-lit. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
A waiting area of some sort should be defined; it should be large enough to accommodate the anticipated number of clients. Client flow issues are addressed to ensure that clients are comfortable when waiting.	The space is set up so that clients waiting for testing will be able to move in and around the area comfortably. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
	The agency has adequate space to accommodate the number of clients seeking testing. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
<u>Not A Required Element but Should Be Considered</u>		
Rapid testing with an FDA approved CLIA waived test can help make HIV testing available to persons who may not choose to access testing in a traditional medical setting.	Is the location where testing will be offered accessible, safe and desirable for the intended target audience? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	

2:5 Provide HIV test counseling in accordance with New York State Public Health Law.*

Required Element	Key Questions to Consider	Feasibility Rating
<p>A copy of the signed informed consent to perform an HIV test is placed in the patient chart.</p> <p>The patient is provided with a copy of the informed consent to perform an HIV test form to review, and additional counseling is provided as needed.</p> <p><u>Additional Consideration</u> Agencies should ensure that adequate staff time is allotted to conduct the informed consent process and provide all required pre- and post-test counseling.</p>	<p>Agency has obtained and plans to use the NYS Informed Consent to Perform an HIV Test form part A & B. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Supervisors ensure staff are prepared to offer streamlined HIV pre-test counseling by training staff in house or sending staff to a NYS approved or sponsored training. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>The agency has an established a counseling protocol that addresses all required elements. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Adequate time is allocated for staff to conduct counseling tailored to the unique needs of each client. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

NOTE: * NYSDOH Regional Training Centers offer training on these topics.

2:6 Conduct and deliver results of confirmatory testing for all patients who test preliminary positive.

Required Element	Key Questions to Consider	Feasibility Rating
In the case of a preliminary positive result, the agency is required to collect and process a specimen for confirmatory testing.	<p>Staff are trained to collect oral fluid or standard venous blood sample for confirmatory testing.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>The agency has an arrangement with a full service lab to conduct the confirmatory testing.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>
Provide the client with post-test counseling appropriate to the outcome of the confirmatory testing.	<p>The agency has the ability to schedule a follow-up appointment with the client for a time when the confirmatory result will be available.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	
Follow-up with clients who do not return to receive their confirmed test result.	<p>The agency has policies and procedures for follow-up if the client does not return to receive the confirmatory test result. Policy includes collecting client contact information, outreach to follow-up on no-shows and aggressive efforts to track and deliver final test results to all clients who require confirmatory testing.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	
All new diagnoses of HIV infection must be reported to the NYSDOH within 21 days of diagnosis.	<p>A process is in place to use DOH Medical Provider HIV/AIDS and Partner/Contact report Form (# 4189) to report all confirmed HIV+ test results to the NYSDOH or NYCDOHMH.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	

2:7 Refer all HIV positive clients to HIV primary and specialty medical care.

Required Element	Key Questions to Consider
The agency must have a documented and proven process in place to ensure that all clients who test confirmatory positive receive seamless transition to HIV primary and specialty care.	Does your agency have a list of health care providers that offer HIV primary care and HIV specialty care? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
Agencies who do not offer HIV primary care may consider developing a memorandum of agreement (MOA) to ensure that clients are entered into care.	Will your agency be able to establish an MOA or formal referral arrangement with one or more of these facilities? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
Clients should have access to primary care within a reasonable length of time.	Has your agency determined a maximum length of time within which all clients should be seen for primary care? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
The agency has a process in place to ensure that the referral to primary care was successful.	Has your agency determined how it will track the status of referrals to primary care? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
<u>Not A Required Element but Should Be Considered</u> Agencies may want to consider having a staff person from a primary care site available to come on-site to explain the primary care services offered to clients and also escort clients to care.	Would one or more of these facilities be willing to come on-site at your agency to explain services or link clients into care? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know

Feasibility Rating
<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

2:8 Provide assistance with partner notification, conduct the required domestic violence screening protocol and comply with HIV disease reporting requirements.*

Required Element	Key Questions to Consider	Feasibility Rating
Staff providing post-test counseling to persons with a confirmed positive test result must provide assistance regarding partner notification.	Staff who will provide post-test counseling have attended training on NYS regulations regarding partner notification. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>
Staff are able to refer clients to established state and city partner notification assistance programs, PNAP and CNAP.	The agency has established a linkage with the local PNAP or CNAP staff and know how to make a referral. Staff are able to request on-site assistance from PNAP/CNAP to facilitate PN services for clients who request assistance. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
A domestic violence screening must be conducted for all named partners.	Staff who provide post-test counseling have attended training on NYS domestic violence screening protocol. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
Referral resources should be available to assist clients who may be victims of domestic violence.	Staff who provide post-test counseling are able to make referrals to local domestic violence shelters and related domestic violence services. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
Under the direction of the provider ordering the HIV test, staff know how to report confirmed cases of HIV infection and known and reported partners to the NYSDOH or NYCDOHMH.	A process in place to ensure reporting of all confirmed HIV+ test results and known and reported partner names. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	

Note: * NYSDOH Regional Training Centers offer training on these topics.

2:9 Refer HIV positive clients to a range of support services including: case management, alcohol and substance abuse treatment, entitlement programs, prevention, housing, legal services and others, as needed.

Required Element	Key Questions to Consider	Feasibility Rating
<p>The agency should have a well-established referral network that includes agency name, address, contact person, phone numbers etc. to meet a wide range of social services needs of people with HIV.</p>	<p>Does your community have an existing resource guide available through the Ryan White CARE Network or other network?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Does your agency have any existing referral agreements with support services providers?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Are there certain needed services for which your agency does not have an existing referral agreement?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>If Yes, which services?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>
<p>The referral directory should be updated on a regular basis.</p>	<p>A process is in place to update the referral directory on a regular basis.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	
<p>A process should be in place to track whether the client actually obtained the intended services.</p>	<p>A process is defined that allows staff to track whether the client obtained the services. Appropriate follow-up will be made in cases where the referral was unsuccessful.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	

2:10 Implement an Exposure Control Plan to protect employees from exposure to bloodborne pathogens, ensure required staff training, provide staff vaccination against Hepatitis B and properly dispose of regulated medical waste.

Required Element	Key Questions to Consider	Feasibility Rating
Agencies that draw blood specimens must have a plan in place to protect staff from possible exposure to bloodborne pathogens in the course of their work.	Does you agency currently have an exposure control plan? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	Complete this column after reviewing column 1 and 2 on this page. Check One Box <input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category. <input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category. <input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category. <input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.
The agency must determine which staff position are exposed to fluids that are associated with transmission of bloodborne pathogens.	Has you agency done an assessment of which staff positions may be exposed to fluids associated with transmission of bloodborne pathogens? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
Designed staff must receive Occupation Safety and Health Administration (OSHA) required training.	Do staff have access to OSHA-required bloodborne pathogen training? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
Designated staff must have access to vaccination against Hepatitis B.	Do staff have access to Hepatitis B vaccination? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
The agency must properly dispose of regulated medical waste (used lancets, specimen loops, used test kits, soiled gloves and other regulated medical waste).	Does the agency have a plan for disposing of regulated medical waste? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	
If conducting blood tests the agency must establish policies and procedures for post-exposure evaluation and follow-up.	The agency has a clearly defined process for evaluating any event of blood exposure and taking steps to avoid future incidents. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	

Section Three - Laboratory Issues

Purpose: The purpose of this section is to help you assess your agency's ability to address laboratory issues associated with offering rapid HIV testing.

3:11 Register with NYS Clinical Laboratory Evaluation Program (CLEP), identify a qualified lab director and obtain needed supplies.

Required Element	Key Questions to Consider	Feasibility Rating
<p>Laboratory operations must be conducted under the supervision of a qualified lab director.</p> <p>Some rapid tests may require the agency to register with NYS CLEP as a limited testing site.</p> <p>In addition to the test kit, the following supplies may be needed for some test kits in order to conduct the rapid test. This is just a sample list, different test kits will require the use of different supplies:</p> <ul style="list-style-type: none"> - Timer(s) - Clean, disposable, absorbent workspace cover - Biohazard waste container - Thermometers - External controls <p>Additional items required for sites conducting blood collection:</p> <ul style="list-style-type: none"> - Antiseptic wipes - Sterile lancets for fingerstick or materials required to obtain a venipuncture - Band aids and gauze pads - Disposable gloves - Sharps containers - Centrifuge to process a plasma specimen - A subject information sheet about the rapid test must be provided to all persons being tested. 	<p>Does the agency have an appointed lab director? (see page 2 for more detail)</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Has the agency completed the registration form, sent \$100 and received confirmation of registration from CLEP?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Has the agency obtained or can the agency obtain the supplies listed?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Does the agency have copies of the subject information sheet and is there a process for ensuring that all clients receive the sheet?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>	<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

3:12 Establish a comprehensive quality assurance plan that ensures proper supervision, outlines step-by step instructions and ensures staff competency in performing and interpreting the test.

Required Element	Key Questions to Consider
A comprehensive quality assurance plan should be written to provide clear, step-by-step guidance for each of the elements listed below.	<p>Does your agency have staff with experience developing quality assurance plans?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>If no, will you seek services from one or more consultants who have this expertise?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>
The plan should outline how quality assurance activities will be documented and how this documentation shall be maintained and made available for review in the event of a site visit from the CLEP.	<p>A clear plan for documenting QA activities is in place.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>
The plan should outline supervisory responsibilities and identify processes for addressing problems if they arise.	<p>A clear chain of supervision is or can be defined and communicated clearly to staff. Staff know who to notify if a problem arises.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>
Written step-by-step instructions for conducting the test have been developed for staff to follow. These instructions address all of the items outlined in the manufacturer's guidelines.	<p>Has your agency obtained materials (video and other documents) from the manufacturer and developed step-by-step instructions specific to implementation in your facility.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>
A process is in place to evaluate staff competency conducting the test and make any needed improvements.	<p>Supervisory staff are prepared to observe staff conducting the test and will evaluate and make corrections as needed.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p>

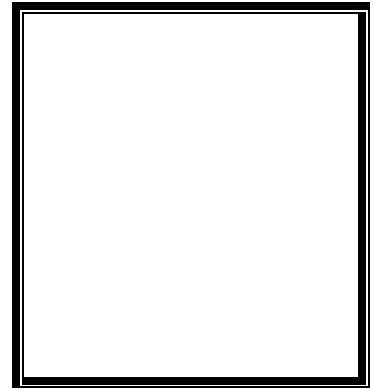
Feasibility Rating
<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

3:13 Establish a quality assurance plan to ensure that testing is being carried out correctly, that results are accurate, and mistakes are found and corrected to avoid adverse effects.

Required Element	Key Questions to Consider	Feasibility Rating
<p>Test kits must be stored at temperatures designated by the manufacturer of the kits.</p> <p>If stored refrigerated, some test kits must come to an operating temperature designated by the manufacturer,, before opening and usage.</p> <p>Test results must be read within the stated timeframes of the manufacturer.</p> <p>Test results must be read in a well-lit room.</p> <p>Some test kits may have external controls that need to be run for HIV 1 and/or HIV 2. These should be run in accordance with manufacturer instructions and may include:</p> <ul style="list-style-type: none"> -When opening a new test kit lot or receiving a new shipment of kits. -For each new operator. -Whenever the temperature of the storage area falls outside of the range designated by the manufacturer. -Whenever the temperature of the testing areas falls outside of the range designated by the manufacturer. -Whenever the temperature of the test kit storage area falls outside of the range designated by the manufacturer. 	<p>Temperature logs for storage areas of test kits and controls have been developed and will be maintained on a regular basis.* <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Temperature logs for the testing areas have been developed and will be maintained on a regular basis.* <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Test result logs have been developed which list kit lot number, the time the test was started and read. Logs will be maintained on a regular basis.* <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>The area where tests will be read is well-lit. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>QA policy and procedure outlines when external controls must be performed. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>External control logs that track the results of external controls and expiration date have been developed and will be maintained on a regular basis.* <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>Invalid tests are tracked, a process is in place to trouble shoot. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know</p> <p>* Sample logs are available from the NYSDOH</p>	<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

-At periodic intervals as established by facility QA plan.

Policies and procedures are established for trouble-shooting whenever a test result is Invalid.



Section Four- Staff Training

Purpose: The purpose of this section is to help you assess your agency's ability to address the range of staff training needs necessary in order to implement rapid HIV testing.

4:14 Staff should receive training in all aspects of the program including HIV test counseling, initial and annual confidentiality training, agency policy and procedure, how to conduct the test and bloodborne pathogens training.

Required Element	Key Questions to Consider
Staff involved in the rapid testing program must be trained in all program policies and procedures outlined in the QA plan.	A plan is in place to train all staff in agency policies and procedures outlined in the QA plan. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
All staff must be fully trained in how to conduct the rapid test.	A plan is in place to train all staff in how to conduct rapid testing. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
All staff conducting finger sticks or drawing blood must attend bloodborne pathogens training.	Is your agency familiar with sources of OSHA bloodborne pathogen training? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
All staff who provide HIV test counseling must be able to address all required counseling elements and must be prepared to: -counsel confirmed HIV+ clients about partner notification, -conduct domestic violence screening - carry out disease reporting requirements under the direction of the clinician ordering the test.	Supervisors ensure staff are prepared to offer HIV counseling in accordance with NYS requirements by training staff in house or sending staff to a NYS approved or sponsored training. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know
Staff should receive initial and annual training in confidentiality protections of Public Health Law Article 27-F and agency policies and procedures.	A process is in place to provide initial and annual training on confidentiality. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know The agency has a standard process for documenting staff attendance at training <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know

Feasibility Rating
<p>Complete this column after reviewing column 1 and 2 on this page.</p> <p>Check One Box</p> <p><input type="checkbox"/> My agency is currently prepared to meet all required elements listed in this category.</p> <p><input type="checkbox"/> My agency would need to make minor modifications to our current practices in order to meet each required element listed in this category.</p> <p><input type="checkbox"/> Significant time, effort or resources will be required to meet one or more of the required elements listed in this category.</p> <p><input type="checkbox"/> One or more of the required elements would be very difficult or impossible for my agency to meet.</p>

Quick Reference of Feasibility Ratings for Each Section

Record on this Quick Reference table the feasibility rating that you assigned to each section of the self-assessment. This will offer you an overview of how prepared your agency is and where you need to focus your efforts if you decide to pursue implementing rapid testing.

		Prepared to meet all required elements.	Need to make minor modifications to current practices.	Significant time, effort or resources will be required.	Very difficult or impossible to meet.
Sec 1, p. 1	Maintain confidential client records.				
Sec 1, p. 2	Staffing requirements.				
Sec 1, p. 3	Reimbursement issues.				
Sec 2, p. 4	Ensure appropriate physical space to conduct rapid testing.				
Sec 2, p. 5	Conduct and deliver results of confirmatory testing for all patients who test preliminary positive.				
Sec 2, p. 6	Conduct and deliver results of confirmatory testing for all patients who test preliminary positive.				
Sec 2, p. 7	Refer all HIV positive clients to HIV primary and specialty medical care.				
Sec 2, p. 8	Provide assistance with partner notification, conduct the required domestic violence screening protocol and comply with HIV disease reporting requirements.				
Sec 2, p. 9	Refer HIV positive clients to a range of support services including: case management, alcohol and substance abuse treatment, entitlement programs, prevention, housing, legal services and others, as needed.				
Sec 2, p. 10	Implement an Exposure Control Plan to protect employees from exposure to bloodborne pathogens, ensure required staff training, provide staff vaccination against Hepatitis B and properly dispose of regulated medical waste.				
Sec 3, p. 11	Register with NYS Clinical Laboratory Evaluation Program, identify a qualified lab director, obtain needed supplies and dispose of regulated medical waste.				
Sec 3, p. 12	Establish a comprehensive quality assurance plan that ensures proper supervision, outlines step-by step instructions and ensures staff competency in performing and interpreting the test.				
Sec 3, p. 13	Ensure that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse effects.				
Sec 4, p. 14	Staff should receive training in all aspects of the program including HIV test counseling, initial and annual confidentiality training, agency policy and procedure, how to conduct the test and bloodborne pathogens training.				

PLEASE PRINT

Agency: _____

Name: _____ Job Title: _____

Phone: _____ Email: _____